

REMARKS

Claims 1-12 and 22-32 remain in this application. All claims stand rejected under 35 U.S.C. 103(a) as unpatentable over Miller in view of DiCaprio et al. Applicant respectfully traverses this rejection.

The MPEP sets out the requirements for a *prima facie* case of obviousness as follows:

2143 Basic Requirements of a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The claimed invention describes a structure that avoids dogboning, a problem not addressed in any of the references. It does this by making the inner balloon shorter than the stent and the outer balloon longer than the stent.

Miller, as seen in Fig. 1 has balloons of equal length. In DiCaprio et al., the outer balloon, the only element actually called a balloon is of the same length as the stent. Even assuming the Examiner is right that combination is suggested, what one ends up with is a structure where inner and outer balloons and the stent are of substantially the same length. The limitation found in claims 1 and 23, "a length of the outer balloon is greater than a length of the stent and a length of the inner balloon is less than the length of the stent," would not be present. There is no teaching or suggestion of this feature in either reference. Only in Applicant's specification does one find this teaching and the reason for it, the prevention of dogboning. Thus, the third criterion set out above is lacking.

Turning to the issue of a suggestion of combination and expectation of success. From the teaching in the art, there is no reason why one would use Miller's two balloon catheter with a stent. What purpose would one expect the inner balloon to perform? Only Applicant's specification gives a reason for two balloons, with a stent and then only when the claimed lengths are present. The Examiner's statement that "*if the inner balloon expands with sufficient force and diameter to crack a hard stenosis [all before bursting], then such a force/diameter would be sufficient to apply a stent to such a region in an artery*" is unsupported conjecture. But even if it is true, what region? Surely there is no teaching of doing it in a region that will "expand the middle portion of said stent." Because the length of the inner an outer balloons is the same in Miller, were a stent mounted and sufficient pressure applied, each balloon would expand the full length of the stent.

Furthermore as stated in MPEP 2143.01:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

In summary, it is clear from the discussion above that all of the criteria needed for a prima facie case of obviousness are missing. At most, what is suggested by the art is to use a balloon catheter to deliver a stent. This was admitted to be known in the specification. That is the only relevant teaching obtainable from DiCaprio. The Examiner admits that otherwise it teaches away. This suggestion of a balloon to deliver a stent does not equate to a suggestion of using the dual balloon catheter of Miller for stent delivery. There is no reason given in either reference for doing so. Specifically, there is no teaching or suggestion, other than in Applicant's specification that dual balloons (when they have the claimed length relationships) will provide an

advantage, let alone prevent dogboning. Thus, there is also nothing that leads one to expect success in reaching Applicant's object. Nor should one expect success because, even when combined, the limitations of the relationship of between the lengths of the stent and the two balloons is missing.

Thus, the two independent claims 1 and 23, both of which contain the limitations discussed above, distinguish over the art and are allowable. The remaining claims depend on one of these claims and should also be allowed.

With regard to claims 2-6, 12, 24-26, and 32, Applicant submits that these further distinguish over the art. A mere contention by the Examiner is insufficient to support a rejection. Applicant is aware of no precedent that would allow this. The limitation must be found in the art. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." MPEP 2143.03. Nor is this a question of inherency. Applicant has selected particular pressures and pressure relationships in order to accomplish his objectives. That is, this is not a question of discovering a new function or property. It is a question of selecting materials with desired properties and using them along with the other claimed features, to provide a device that will accomplish a result of preventing dogboning

In view of the above, Applicants believe that all claims remaining in this application are in condition for allowance. Thus, reconsideration of the Examiner's rejections and allowance of all remaining claims is respectfully solicited.


The Examiner is invited to call the undersigned at (202) 220-4200 to discuss any information concerning this application.

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The Office is hereby authorized to charge any additional fees under 37 C.F.R. § 1.16 or § 1.17 or credit any overpayment to Deposit Account No. 11-0600.

Respectfully submitted,

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